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THE EXPANDING “COSMECEUTICAL” CONUNDRUM:
THE GROWING NEED FOR HEIGHTENED FDA
REGULATIONS IN THE FACE OF MODERN DAY
COSMECEUTICALS

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Abstract

The popularity and prevalence of cosmeceutical products is growing at an unprecedented rate both domestically and abroad. In the United States, cosmeceuticals are typically regulated as cosmetics even though these products often offer drug-like benefits. As the efficacy claims, technology and science used in these products continues to advance, the application of the pure cosmetics regulatory scheme under the FDCA grows increasingly problematic. This paper aims to discuss why the existing legal system is ill equipped to properly monitor the modern cosmeceutical industry and it attempts to suggest possible ways to improve the oversight of these products. Part I sets the stage by examining the current cosmeceutical industry. Part II reviews the historical and current regulatory framework of both cosmetics and drugs. Part III looks at two modern day cosmeceuticals, eyelash growth products and anti-age creams with stem-cell technology, to further analyze why existing regulations are insufficient to protect consumers. Part IV proposes several possible modifications to the current regulation of cosmeceuticals, ultimately recommending the creation of a new cosmeceuticals category under the FDCA. Part V concludes.

Part I: Introduction

Professor Albert Klingman of the University of Pennsylvania first popularized the term “cosmeceuticals” in 1979.¹ The term was initially coined to describe a class of face creams that claimed to do more than merely “decorate or camouflage,” given the inclusion of *active* ingredients, which were intended to provide additional health benefits.² In the past few decades, this category of products has greatly expanded to reflect a growing array of personal care products that remain regulated as cosmetics but are marketed as offering drug-like advantages. Ranging from creams and serums that are “packed with extra ingredients, like Alpha Hydroxy Acids, Ester-C, and copper peptides said to have therapeutic benefits,”³ to applications that promise to moisturize and thicken hair, the term cosmeceutical has gained significant momentum as it appropriately describes the current realities of the modern cosmetics industry.

Today, the cosmeceutical market represents one of the fastest growing segments within personal care products. According to one market research company, cosmeceutical skincare products alone accounted for more than \$6.4 billion in domestic sales in 2004, with an estimated increase to over \$16 billion by 2010.⁴ Another consulting firm noted, “the global market for cosmeceuticals is

¹ Albert Klingman, *Cosmeceuticals: Do We Need a New Category?* in COSMECEUTICALS 1 (Peter Elsner & Howard I. Maibach, eds., 2000).

² See Klingman, *supra* note 1, at 4.

³ Erika Kawalek, *Artfully Made-Up*, 2005-DEC Legal Aff. 54. (2005)

⁴ Kawalek, *supra* note 2.

growing nearly twice as fast as the overall cosmetics and toiletries market.”⁵

Fueled by an aging generation of baby-boomers and a growing obsession with youthfulness and wellness,⁶ these products, which are often more readily available than prescription drugs, present an extremely attractive option to a wide consumer base. Furthermore, given the recent advancements in scientific technologies such as the development of nanotechnology, DNA technology and stem cell research, the potential for new products is overwhelming. Hence it is no surprise that established cosmetics companies, new biotech manufacturers and even some traditional pharmaceutical companies have flushed the market with the production of numerous cosmeceuticals in an attempt to take advantage of this extremely lucrative, high-margin business.

Unfortunately, the law in this area has been slow to react to the changes and modernization of cosmetics. The Food, Drug and Cosmetic Act (FDCA), the statute primarily responsible for the regulation of cosmetics, does not currently recognize cosmeceuticals as a valid legal category. Instead, the FDCA retains its original framework, classifying an article as either a drug or a cosmetic (and very occasionally, as both) based on the product’s intended use.⁷ More specifically, a product will be deemed a cosmetic if it is *intended* to be:

⁵ Scientia Advisors Press Release, available at http://www.scientiaadv.com/pr_2009-11-04.php (last visited March 30, 2011)

⁶ Victoria Farren, *Removing the Wrinkle in Cosmetics and Drug Regulation: A Notice Rating System and Education Proposal for Anti-Aging Cosmeceuticals*, 16 Elder L.J. 375, 376 (2009).

⁷ Food and Drug Administration Website, <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ucm074201.htm> (last visited March 30, 2011)

“(1) rubbed, poured, sprinkled, or sprayed on, or introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the *appearance* and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.”⁸

By contrast, a product is regulated as a drug if it is:

“(b) intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (c) articles (other than food) *intended to affect the structure or any function of the body* of man or other animals.”⁹

Since cosmeceutical products tend to be topical and carefully positioned as only *intending* to affect one’s temporary appearance, manufacturers are generally able to evade the much stricter regulatory approval process imposed on drugs. However it seems that from a functional perspective, these products are better described as actually falling somewhere along the cosmetic-drug spectrum. Thus, simply permitting cosmeceuticals to continue to be regulated under the minimal cosmetics standard is highly problematic. Not only is the threat of a greater number of inadequately tested products reaching the market amplified, but the number of manufacturers that are able to benefit from making deceptively unsubstantiated claims at the expense of the consumers’ pocketbooks is also immense. In light of this new generation of cosmetics, the FDA should strongly consider amending its current approach to the regulation (or rather lack thereof) of cosmeceuticals. More oversight is needed to appropriately monitor the safety of these products that use newly discovered ingredients and technologies, which may present unknown risks and effects. Additionally, the FDA must consider

⁸ 21 U.S.C. sec. 321(i) (emphasis added).

⁹ 21 U.S.C. sec. 321(g)(1) (emphasis added).

ways in which it can better protect consumers from the increasingly bold statements about cosmeceutical efficacy in situations where there is insufficient data supporting such claims.

This paper aims to discuss why the existing legal system is ill equipped to properly monitor the growing cosmeceutical industry and to suggest possible ways to improve the oversight of these products. Part II reviews the historical and current regulatory framework of cosmetics and drugs. Part III discusses the insufficiency of the existing approach from both a safety and economics perspective through an analysis of several modern-day cosmeceutical examples, including the recently trendy eyelash enhancer products and the newest fad in anti-aging creams: the use of stem-cell technology. Part IV proposes several possible modifications to the current regulation of cosmeceuticals, ultimately recommending the creation of a new cosmeceuticals category under the FDCA. Part V concludes.

Part II: Historical and Current Regulation of the Cosmetics Industry

The Food, Drug and Cosmetic Act (FDCA) was enacted in 1938.¹⁰ The passage of the FDCA represented the first time the FDA was given power to regulate the cosmetics industry.¹¹ Several tragedies involving dangerous cosmetics such as the depilatory Koremlu Cream and the infamous Lash Lure

¹⁰ Peter Barton Hutt, *Legal distinction in the United States Between a Cosmetic and a Drug*, in COSMECEUTICALS 223, 225 ((Peter Elsner & Howard I. Maibach, eds., 2000).

¹¹ Laura A. Heymann, *The Cosmetic/Drug Dilemma: FDA Regulation of Alpha-Hydroxy Acids*, 52 Food & Drug L.J. 357, 361 (1997)

product, both of which contained highly poisonous chemicals, provided the necessary catalyst for the change.¹² While bringing cosmetics under the control of the FDA represented an important and necessary step in promoting public safety, the actual contours surrounding the regulation of cosmetics were (and are) quite limited.¹³ Under the FDCA, cosmetics are “prohibited from being adulterated or misbranded, but, with the exception of color additives, they are not subject to premarket approval, safety or efficacy testing, or good manufacturing practices.”¹⁴ Astonishingly, the FDCA remains largely unchanged from its original 1938 form as to the cosmetic portions of the Act.¹⁵ Despite the significant changes that have occurred in the science involved in producing cosmetics, which was even recognized by the Commissioner of Food and Drugs back in 1988, the governing law has nonetheless stayed relatively constant.¹⁶ Cosmetics continue to represent the least restrictive category under FDA supervision, and to this day, cosmetics represent the only “major FDA-regulated product group that does not have its own center within the FDA.”^{17 18}

¹² Amity Hartman, *FDA’s Minimal Regulation of Cosmetics and the Daring Claims of Cosmetic Companies that Cause Consumers Economic Harm*, 36 W. St. U. L. Rev. 53, 55 (2008)

¹³ *Id.*

¹⁴ Jacqueline A. Greff, “Regulation of Cosmetics that are Also Drugs,” 51 Food & Drug L.J. 243 (1996)

¹⁵ Peter Barton Hutt, *supra* note 10, at 237.

¹⁶ Heymann, *supra* note 11, at 370.

¹⁷ Greff, *supra* note 14, at 248.

¹⁸ Cosmetics continue to be primarily regulated by the Center for Food Safety and Applied Nutrition (CFSAN), though the Center for Drug Evaluation and Research (CDER) has concurrent jurisdiction over products that purport to be cosmetic but meets the definition of a drug. See CDER-CFSAN Cosmetic Agreement available at <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/ComplianceEnforcement/ucm2005170.htm> (last visited April 1, 2011).

Specifically, the FDCA operates by imposing intent-centered definitions, which are used to distinguish a cosmetic from a drug.¹⁹ Thus most products will fall into either the drug category *or* the cosmetics category, although since the definitions are not mutually exclusive, some products may need to satisfy both standards.²⁰ Because there is a sharp contrast in the level of regulation and FDA involvement depending on whether an article is a drug or cosmetic, there is a strong incentive for cosmeceutical manufacturers to avoid the much harsher drug framework by attempting to place their products within the confines of the cosmetics definition. As noted above, the main factor determining a product's categorization as either a drug or cosmetic is the product's *intended use*.²¹ Namely, if an article is intended to affect the *structure or function* of the body based on its labeling and advertising, the product will be regulated as a drug; by contrast, if a product only makes vague claims about how it will impact one's appearance, it will likely be classified as a cosmetic.²² Thus, "whether a product actually has an effect on a structure or function of the body [is] irrelevant: If the manufacturer claims it does, it is considered a drug; if it does not, it is considered a cosmetic. A dangerous chemical for which only cosmetic claims were made might avoid premarket regulation, whereas a claim that a product consisting

¹⁹ See generally, 21 U.S.C. sec. 321.

²⁰ Klingman, *supra* note 1, at 3.

²¹ Greff, *supra* note 14, at 253.

²² Heymann, *supra* note 11, at 370.

wholly of water would ‘plump up skin cells’ would cause the product to be regulated as a drug.”²³

Drug regulation under the FDCA is extremely time-consuming and subject to extensive oversight. Cosmetics on the other hand are only required to adhere to minimal FDA-established requirements. More specifically, in the areas of “approval requirements, good manufacturing practices, registration and labeling,”²⁴ drugs are subject to much stricter regulatory hurdles. For instance, drugs must receive premarket approval by the FDA before they are permitted to reach the market.²⁵ During this premarket review process, the product is vetted and scrutinized by the FDA as to the safety and efficacy of the product.²⁶ Only after the agency has tested and approved the drug will it be available to end-consumers.

Additionally, drug manufacturers are *required* to register their manufacturing establishments and all drug products with the FDA (specifically with the Secretary of the Department of Health and Human Services).²⁷ By mandating registration, the FDA can properly track and monitor drugs available on the market. Drug producers must also conform to current good manufacturing practice (GMP) requirements, which are set forth in FDA regulations,²⁸ and these

²³ *Id.* at 366.

²⁴ Farren, *supra* note 6, at 383.

²⁵ *Id.*

²⁶ Heymann, *supra* note 11, at 364.

²⁷ Stephen H. McNamara, *Regulation of Cosmetics in the United States – An Overview*, in THE COSMETICS INDUSTRY: SCIENTIFIC AND REGULATORY FOUNDATIONS, 4, 11 (Norman F. Estrin, ed., 1984).

²⁸ *Id.*

companies are required to report product-related injuries to the agency on an on-going basis.²⁹ Finally, drugs are subject to onerous labeling requirements given the FDA requires any drug product to identify active ingredients on both its packaging and the immediate container of the drug.³⁰

In contrast to these rigorous requirements that have been established for drugs, cosmetics are subject to a much looser regulatory framework. Most significantly, cosmetics do not need to pass any premarket clearance before they are available on the market, with a limited exception for color additives and certain prohibited ingredients.³¹ Because there is no FDA-enforced premarket approval system, the potential dangers of a cosmetic are often not discovered until after the product has already been on the market and caused harm to consumers.³² Moreover, the lack of premarket review implies that cosmetic manufacturers are not even required to prove their products are generally safe or effective in what they claim to do before they are sold to naïve consumers.³³

Instead, protection of the public is achieved primarily through the adulteration and misbranding provisions of the FDCA, and “the requirement that a cosmetic ingredient or product that has not been adequately substantiated for safety prior to marketing be conspicuously labeled ‘Warning -- The safety of this product has not been determined.’”³⁴ Cosmetics are also subject to The Fair

²⁹ Greff, *supra* note 14, at 247.

³⁰ *Id.* (quoting 21 U.S.C. 321(g)(1))

³¹ Farren, *supra* note 6, at 383.

³² Heymann, *supra* note 11, at 363.

³³ *Id.*

³⁴ Greff, *supra* note 14, at 248.

Packaging and Labeling Act of 1973, and thus cosmetic manufacturers are required to include ingredient statement labels on the products that are sold to consumers.³⁵ In particular, the FDA regulations provide that cosmetic products must include the following information: “the cosmetic name, quantity, name and place of business of the manufacturer and ingredients listed in order of predominance.”³⁶ However, unlike drug labels, pure cosmetics are not required to separately list any active ingredients used in the product (unless of course, the product is also classified as an over-the-counter drug).³⁷

Additionally, unlike their drug counterpart, cosmetics are not subject to any FDA established GMP requirements nor are cosmetic manufacturers required to register their establishment or their product formulations with the agency.³⁸ Although cosmetic companies may voluntarily register themselves with the Voluntary Cosmetic Registration Program, the FDA's Office of Cosmetics and Colors state that only about 35% to 40% of cosmetics manufacturers participate in the program.³⁹ Cosmetic companies also do not have the duty to report any injuries or complaints it receives from consumers regarding its products, though again, the company may report such incidents to the Voluntary Cosmetic Reporting Program.⁴⁰ As this comparison makes obvious, the greatest difference

³⁵ Roseann B. Termini and Leah Tressler, *American Beauty: An Analytical View of the Past and Current Effectiveness of Cosmetic Safety Regulations and Future Direction*, 63 Food & Drug L. J. 257, 263 (2008).

³⁶ *Id.* (quoting 21 C.F.R. § 701.10; § 701.12 (2007)).

³⁷ Farren, *supra* note 6, at 384.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ Hartman, *supra* note 12, at 64.

between the regulation of drugs and cosmetics is the level of discretion and voluntariness afforded to cosmetics that is not tolerated in the drug context.

In the wake of the rapidly growing number of cosmeceuticals offered in the marketplace, the existing classification system used to distinguish cosmetics from drugs is insufficient to address these products, which seemingly fall somewhere between the two categories. As a result of the stale, bifurcated FDCA definitions, the current legal system is both inefficient and ineffective at regulating cosmeceuticals, for which “often no more than a fine line exists between cosmetic and drug classification.”⁴¹ Given the vastly divergent regulatory requirements placed on drugs and cosmetics, a cosmeceutical producer will clearly try to stay on the cosmetics side of the divide, thereby avoiding the expensive pre-approval and compliance requirements imposed on drugs. And because categorization is based on intended use, the FDA will be limited in its ability to force an article under the stricter drug definition. Unless the FDA is able to scare the manufacturer into toning down efficacy claims through warning letters, the only other means by which it can properly regulate a cosmeceutical is if the agency chooses to bring a suit challenging the misclassification of the product as a cosmetic rather than as a drug.⁴²

⁴¹ Farren, *supra* note 6, at 385.

⁴² Bryan A. Liang and Kurt M. Hartman, *It's only skin deep: FDA Regulation of Skin Care Cosmetics Claims*, 8 Cornell J.L. & Pub. Pol'y 249, 252 (1999).

However this approach is costly, and does not always lead to consistent outcomes as demonstrated by the Wrinkle Remover Cases of the 1960s.⁴³ In three very similar, closely litigated cases involving cosmetic products that all contained solutions of bovine serum albumin in water, the FDA was successful in convincing only two of the three courts to categorize the respective product as a drug based on the manufacturer's claims, which suggested an intent to affect the structure of the body (e.g. "a face lift without surgery").⁴⁴ The incongruous treatment of virtually identical products demonstrates the inadequacy of the current regulatory process, especially in the face of an increasing number of categorically ambiguous cosmeceuticals. Protecting consumers in this limited, haphazard way is simply not good enough. Furthermore, due to limitations in FDA resources and the historically weak FDA enforcement of the regulations promulgated under the FDCA, "cosmetics companies have been free to make more bold and daring claims with each new advertisement and still avoid having its products classified as a drug."⁴⁵ Hence if this binary framework continues to dictate the regulatory treatment of cosmeceuticals, these manufacturers are unfairly permitted to have their cake and eat it too. By selling products that "look, sound, feel--and cost--a lot like drugs or other FDA-approved therapies,"⁴⁶ but

⁴³ See generally, Hutt, *supra* note 10, at 229-30; Liang and Hartman, *supra* note 42, at 252-255.

⁴⁴ Greff, *supra* note 14, at 252 (summarizing the court holdings in: *United States v. "Line Away,"* 284 F. Supp. 107 (D. Del. 1968), *aff'd*, 415 F.2d 369 (3d Cir. 1969); *United States v. "Sudden Change,"* 288 F. Supp. 29 (E.D.N.Y. 1968), *rev'd*, 409 F.2d 734 (2d Cir. 1969); *United States v. "Magic Secret,"* 331 F. Supp. 912 (D. Md. 1971)).

⁴⁵ Hartman, *supra* note 12, at 60.

⁴⁶ Kawalek *supra* note 3, at 54.

are only subject to lenient cosmetics regulations, cosmeceutical makers are able to economically benefit, while consumers are unnecessarily exposed to potential physical and economic harm. The heightened stakes associated with inadvertently permitting cosmeceuticals to enter the market without “information as to safety precautions, adverse side-effects, or efficacy,”⁴⁷ emphasize the need for greater FDA oversight of these products so that they are properly monitored when they are introduced in the marketplace, instead of only after the fact.

Part III: Modern Day Cosmeceuticals – Eyelash Enhancing Serums, Anti-Aging Creams with Stem Cell Technology and DNA Repair Lotions

To further demonstrate the extent to which existing regulations fail to satisfy the needs of the current cosmetic landscape, this section will analyze several of the new popular cosmeceuticals that are already available on the market. The products discussed highlight the regulatory gap in the present system, and exemplify why the FDA needs to impose a greater level of regulation specifically on cosmeceuticals.

A. Eyelash Growth/Enhancing Products: Latisse vs. Competing Cosmeceuticals

For centuries, women have looked for ways to make their eyelashes appear darker, longer and fuller. Products like mascara and false adhesive lashes (which now include professional lash extensions) have traditionally satisfied this desire. However in the past few years, a new batch of products

⁴⁷ Liang and Hartman, *supra* note 42, at 258.

have been developed and marketed that claim to actually stimulate the lengthening and thickening of one's own lashes. These eyelash growth serums arguably go beyond enhancing one's appearance as they are said to promote actual lash growth.⁴⁸ Yet of the many products that are available for purchase,⁴⁹ only one has been FDA-approved as a legitimate eyelash growth drug.

In December of 2008, the FDA approved the drug Latisse (manufactured by the pharmaceutical giant Allergan), a prescription treatment that can be used to promote eyelash growth and make them "longer, thicker and darker."⁵⁰ Latisse contains the active ingredient bimatoprost ophthalmic solution, a prostaglandin analogue, which is also used in Allergan's glaucoma drug Lumigan.⁵¹ Though the formula of the two drugs is nearly identical, the application of the two differs as Latisse is used as a topical serum applied on the upper eyelid margin at the base of the eyelashes, whereas Lumigan is administered as an eyedrop.⁵² In the fall of 2009, less than a year after the product's launch, Allergan received a warning letter from the FDA stating that many of the claims included on the Latisse website were misleading and failed to adequately reflect the risks associated with the product, in violation of the FDCA (21 U.S.C. 352(a) & 352(n)) and several FDA implementing regulations (21 CFR 202.1(e)(3)(i); (e)(5) & (e)(7)(viii)).⁵³

⁴⁸ See e.g. <http://www.eyelash-growth.com/> (last visited April 3, 2011).

⁴⁹ *Id* (listing and reviewing 20 lash growth products).

⁵⁰ Latisse Home Page, www.latisse.com (last visited April 8, 2011).

⁵¹ Catherine Saint Louis, *Long Lashes Without Prescription, but with Risks*, THE NEW YORK TIMES, (May 2, 2010), <http://www.nytimes.com/2010/05/02/health/02latisse.html>.

⁵² See Latisse Prescribing Information Pamphlet, *available at* www.latisse.com

⁵³ FDA Warning Letter to Latisse, *available at*

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Enforc>

Some of the serious risks associated with this product that were not properly addressed included “effects on intraocular pressure, permanent iris pigmentation, semi-permanent lid pigmentation, hair growth outside the treatment area, intraocular inflammation, macular edema, contamination of Latisse or applicators, and potential adverse reactions with contact lenses.”⁵⁴ The FDA requested that Allergan “immediately cease the dissemination of violative promotional materials for Latisse ...and submit a written response ... explaining [its] plan for discontinuing the use of such violative materials.”⁵⁵

The FDA’s treatment of Latisse demonstrates the high level of oversight and consumer protection that is provided for drug compounds. Not only was Latisse subject to a comprehensive premarket approval process, but it has also been subject to ongoing FDA monitoring and surveillance. Moreover, when the FDA finally did approve Latisse for marketing, “they made a determination that the side effects or misuse or inappropriate use could cause harm, and that’s why they restricted it to a prescription drug...if it was completely safe to use without doctor supervision, they would have deemed it over-the-counter.”⁵⁶ It is thus quite startling to discover that there are a number of similar lash-growing *cosmetic* products currently available on the market that have not been subject to the same regulatory rigors as Latisse. Two competing cosmetics products in

ementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/UCM182628.pdf (September 10, 2009).

⁵⁴ See Latisse Prescribing Information pamphlet, *supra* note 52.

⁵⁵ FDA Warning Letter to Latisse, *supra* note 53.

⁵⁶ Catherine Saint Louis, *supra* note 50 (quoting Carmen A. Catizone, the executive director of the National Association of Boards of Pharmacy, which represents state agencies that regulate pharmacies and pharmacists).

particular, Athena Cosmetics' Revitalash and Jan Marini's Age Intervention Eyelash Conditioner are especially interesting because they were both originally sold with formulas containing the same drug ingredient bimatoprost. The Jan Marini product was launched in 2005,⁵⁷ while Revitalash was introduced in 2007.⁵⁸ Notably, both of these cosmeceuticals were offered for sale *before* the FDA had officially approved Latisse, and both went to market without any FDA-sponsored testing given their positioning as cosmetics. Since cosmetics are not required by the FDA to list the side effects associated with their products (presumably because the majority of traditional cosmetics should not cause any), these cosmeceuticals were also available to consumers without proper safety warnings. When one recognizes the gravity of the potential risks that may stem from the misuse of a product containing a prescription ingredient like bimatoprost, it is quite shocking to think that these unregulated products were so easily allowed on the market.

In November of 2007, the FDA finally confiscated over 12,000 applicator tubes of Jan Marini's Age Intervention Eyelash Conditioner as "an unapproved and misbranded drug [given] Jan Marini Skin Research promoted the product to increase eyelash growth... and as an adulterated cosmetic [given] the product's [inclusion of] bimatoprost."⁵⁹ The FDA claimed it feared for the "safety of the

⁵⁷ See Jan Marini, <http://www.janmarini.com/us/viewPrd.asp?idproduct=50> (last visited April 1, 2011).

⁵⁸ Katharine Griffiths, *The Innovator*, COSMETIC SURGERY & AESTHETICS TODAY (Feb. 23, 2011) <http://www.cosmeticsurgerytoday.co.uk/features/view/10536/the-innovator/>

⁵⁹ FDA News Release, *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm109028.htm>

consumers who purchased the product,”⁶⁰ however by the time the product was seized by the FDA, the sale and production of this particular version of the product was already banned by the California Department of Public Health’s Food and Drug Branch.⁶¹ In fact, Jan Marini had already reformulated its lash enhancer product so that it was based on non-prostaglandin technology consisting of a proprietary blend of peptides.⁶² That the FDA only took action after the fact demonstrates just how ineffective the current regulatory structure is in monitoring cosmeceuticals in an appropriate and timely fashion. Additionally, the initially disparate treatment of Latisse and these virtually identical cosmeceutical products, further highlights the serious gap that exists in the FDA framework.

Perhaps even more concerning is the fact that the FDA did not take similar action against any other eyelash-enhancing cosmetic product, even though several other brands contained similar prostaglandin ingredients.⁶³ Some reports claim that the FDA’s action against Jan Marini’s product was enough to prompt the makers of Revitalash and the creators of Enormous Lash (yet another eyelash enhancing serum) to voluntarily reformulate their products.⁶⁴ However based on several other consumer review sites, it is unclear whether Revitalash actually reformulated its product to get rid of all forms of prostaglandin

⁶⁰ Hartman, *supra* note 12, at 67

⁶¹ *Id.*

⁶² See Jan Marini, <http://www.janmarini.com/us/viewPrd.asp?idproduct=50> (last visited April 1, 2011)

⁶³ Hartman, *supra* note 12, at 68.

⁶⁴ Amy Sillup, *Super Long Eyelashes*, (Jan. 24, 2010)

<http://www.suite101.com/content/super-long-eyelashes-a193404#ixzz1IVJ1Mlql>

analogues, or simply replaced its use of bimatoprost with Trifluoromethyl Dechloro Ethylprostenolamide, a prostaglandin derivative that works in a similar fashion to stimulate lash growth.⁶⁵ Perhaps the fact that Allergan sued seven cosmetic companies including Athena Cosmetic's and the makers of Enormous Lash, for an alleged patent infringement based on their use of prostaglandins in their cosmeceutical products,⁶⁶ suggests the FDA did not go far enough to protect consumers from these under-regulated eyelash growth products. In any case, resting the safety of consumers' health on the conscience of manufacturing companies is a precarious position to take. Rather, a more effective and less risky approach would be for the FDA to subject all such products to a stricter and more uniform review.

Furthermore, even if several cosmeceutical manufacturers removed the potentially dangerous prostaglandin ingredients from their products subsequent to the FDA's seizure of Jan Marini's product, these companies continue to sell products they ostensibly claim promote *eyelash growth*. Although some manufacturers are careful to state that their products are only intended to "enhance the appearance of eyelashes, or deliver gorgeous, dense and lush-looking eyelashes,"⁶⁷ oftentimes, they also include before and after pictures, user

⁶⁵ See e.g. <http://www.eyelash-growth.com/reviews/revitalash/>; <http://www.eyelashgrowthnow.com/revitalash-eyelash-conditioner/>; and <http://eyelashgrowthcenter.com/eyelashes/products/revitalash.html> (last visited April 4, 2011)

⁶⁶ *Patent lawsuit filed by Allergan* (Nov. 20, 2007), BLOOMBERG NEWS, <http://articles.latimes.com/2007/nov/20/business/fi-allergan20>

⁶⁷ See e.g. Features Description for Marni Lash Eyelash Conditioner at <http://www.janmarini.com/us/viewPrd.asp?idproduct=50>.

testimonials and doctor-backed stamps of approval in their marketing materials, which insinuate how these products are really intended to work. Consequently, this may lead to rampant consumer confusion over which products are actually safe, effective and properly regulated. The additional fact that many of these cosmeceuticals are priced similar to the Latisse drug despite unsubstantiated efficacy claims, at a minimum, exposes consumers to unnecessary economic harm. The trouble again seems to stem from the extremely different legal treatment that is afforded to products based on whether it is defined as a drug or cosmetic. When remarkably similar products are regulated in diametrically opposite manners, simply due to the promotional materials of the manufacturers, the failures of the existing regulatory regime are made grossly apparent. All cosmeceuticals need to be given comparable regulatory treatment if the FDA wants to efficiently and effectively deal with the problems that can arise from such products.

B. The Latest Anti-Aging Craze: Stem Cells as the New Alpha-Hydroxy Acids

In the early 1990s, products containing Alpha-Hydroxy Acids (AHAs) became ubiquitous on the mass market and they were heralded in as THE anti-aging solution.⁶⁸ When topically applied, AHAs exfoliate the top layer of skin, thereby exposing the “fresher-looking skin underneath...[providing a] milder cosmetic version of a chemical peel at home.”⁶⁹ Because AHA products were

⁶⁸ Farren *supra* note 6, 389.

⁶⁹ *Id.*

generally categorized as cosmetics, they were able to avoid FDA premarket clearance, and thus the negative side effects and health risks associated with high concentrations of AHAs were not fully known until after the product had already widely penetrated the market. The side effects, which included “severe redness, swelling, burning, blistering, bleeding, rash, itching and skin discoloration,”⁷⁰ made it obvious that AHAs were non-traditional cosmetics and “unlike anything else ever introduced onto the cosmetic market on such a wide scale.”⁷¹ As the number of complaints grew, it became clear that AHAs did “exert an effect on the skin... affecting the structure and function of the body and that they should be regulated as drugs.”⁷² However, because the treatment of cosmeceuticals remained subject to the drug/cosmetic distinction, the FDA was limited in how it could properly address the AHAs problem. Ultimately, the FDA chose not to attempt a forced drug classification on these products but rather only recommended labeling guidance (specifically, the inclusion of a “sunburn alert” warning) for cosmetics containing AHAs.⁷³ This ultimately unsatisfactory resolution of the treatment of AHAs, one of the first major anti-aging cosmeceuticals, has left the door open for the continued inadequate legal treatment of anti-aging products.

Given the rapid pace of science and technology development, it seems

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Greff, *supra* note 14, 257.

⁷³ Guidance for Industry Labeling for Topically Applied Cosmetic Products Containing Alpha Hydroxy Acids as Ingredients, *available at* <http://www.fda.gov/Cosmetics/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ucm090816.htm#cos>.

that every few years, a new and even better anti-aging miracle cosmeceutical is introduced into the marketplace for consumers to try. Though these products may just be marketing gimmicks that attempt to trick the gullible into buying yet another expensive but ineffective skincare product, the problem is that in this new era of cosmetics with its constantly evolving technologies, we often do not know whether the product is safe, dangerous, or simply ineffective until after it has already been introduced. The latest craze in anti-aging appears to be skincare creams containing “stem cells,” which have become quite vogue in the past few years.⁷⁴ Stem-cell technology is said to be “revolutionizing skin care” and manufacturers of stem cell creams are claiming that their emulsions are capable of “rejuvenat[ing] skin by awakening your body’s own reservoir of undifferentiated stem cells.”⁷⁵ One stem cell cream company stated in a press release that its “recorded sales are skyrocketing as the word gets out of the product.”⁷⁶

Like their AHAs predecessors, the problem with these new stem cell creams is that they are able to reach the market under the lax cosmetics definition while the efficacy and science behind these products is not fully known. Even the exact technology used in these creams remains ambiguous. Some products available on the market such as the Bio Therapie cream and the PhytoCellTec line of creams offered by the Mibelle Biochemistry Company, use

⁷⁴ Simon Crompton, *New Beauty Craze, Stem Cells*, THE TIMES (July 18, 2009), http://women.timesonline.co.uk/tol/life_and_style/women/beauty/article6716673.ece

⁷⁵ Stem Cells: the Future of Skin Rejuvenation ... New Wrinkle Creams Pioneer Anti - Aging Technology Stem Cell Research, 4018 2008 WLNR 2379424 (2008).

⁷⁶ Stem Cell Creams Are the New Wave of Anti-Aging and Anti-Wrinkle Face and Eye Creams, Health & Med. Wk., 2011 WLNR 4772998 (2011)

plant stem cells that are said to help combat aging by positively impacting the vitality of human skin stem cells.⁷⁷ Several other products, such as Stem Cell Therapy by BioLogic Solutions and Amatokin Emulsion utilize “stem cell technology,” using peptides to activate the deeper layers of skin that contain adult stem cells and stimulate them to produce fresh new skin cells.⁷⁸ Still, another group of international biotech firms including RNL Bio and Prostemics have created cosmetics that contain stem cell culture fluid – “liquid that has been used to culture stem cells but does not actually contain any human tissue.”⁷⁹ However, the fact that no stem cell cream *currently* uses human stem cells does not necessarily mean they will never use them in the future. The possibility that some manufacturers will explore this option is not entirely out of the picture (absent stricter regulation), especially if companies “attempt a race to the top...to achieve a more drastic effect,”⁸⁰ as was seen with the AHAs products.

Yet even when we limited the inquiry to the existing products available on the market today, it is not entirely clear that consumers are not at risk. For example, the stem cell culture fluid used in some products is extracted from fat tissues sourced from hospitals; because the fat tissues come from various liposuction surgeries, there may be serious risks of viral and bacterial

⁷⁷ Mibelle Biochemistry, <http://www.mibellebiochemistry.com/products/latest-developments/PhytoCellTec.php>; PhytoCellTec, <http://www.phytocelltec.ch/pctmalusdomestica.php>.

⁷⁸ Amatokin, <http://amatokinstore.com/about-amatokin.php>.

⁷⁹ Seo Ji-eun, *A Miracle Salve or Another Stem Cell Fraud?*, KOREA JOONGANG DAILY (March 17, 2010), <http://joongangdaily.joins.com/article/view.asp?aid=2917887>

⁸⁰ Heymann, *supra* note 11, at 359.

contamination in the materials.⁸¹ Concerned with the potential health risks that could be posed by this unfamiliar ingredient, the Korean Food and Drug Administration temporarily banned the use of culture fluids in cosmetics.⁸² Though they are no longer on the banned ingredients list, the KFDA has continued to study the best way to regulate the newly developed stem-cell creams.⁸³ The American FDA should similarly explore more stringent means of regulating these new cosmeceuticals. Although the FDA has taken some action, and sent a warning letter to one stem cell cream manufacturer in early March 2011, claiming that the promotions contained on JabaLabs's websites caused their products to be drugs,⁸⁴ the company simply had to correct its labeling violations by toning down the claims made for its product, to avoid enforcement action.⁸⁵ The FDA did no more to inquire into the products' safety or efficacy and the manufacturer is still able to continue selling its creams to consumers. Arguably this is not enough to protect consumers from potential risks.

Even if the manufacturers of stem cell creams are only engaging in mere puffery, in the face of such new and untested science, the FDA cannot permit these products to escape close scrutiny by simply hiding under the cosmetics-definition. Without some form of premarket screening or ongoing FDA oversight,

⁸¹ Kim Tong-Hyung, *Safety Debate Heats up on Stem Cell Cosmetics*, KOREA TIMES 2009 WLNR 9144808 (2009).

⁸² Seo Ji-eun, *supra* note 79.

⁸³ *Id.*

⁸⁴ Jaba Labs 3/1/11 Warning Letter, *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm246086.htm>

⁸⁵ Jaba Labs Close out Letter 3/30/11, *available at* <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm250292.htm>

consumers will likely discover the potential range of adverse side effects, both short-term and long-term, after the fact. And as to cosmetics, the FDA currently has no authority to directly recall these products, even if they are later found to be harmful.⁸⁶ The aggressive marketing used for these products like “the first anti-aging cream that will help restore the potential of skin stem cells and bring back the skin of youth”⁸⁷ despite uncertainties in effectiveness, coupled with the potential health dangers that may exist in this unfamiliar technology, present the extremely detrimental combination of imposing serious harm on consumers’ health and finances. Products like these new stem cell creams again demonstrate the need for greater FDA regulation over emerging cosmeceuticals, and call for reform to ensure harms are detected before harms are borne by consumers.

Part IV: Proposals for Possible Reform and the Case for a New Cosmeceutical Subcategory

The argument in support of modifying existing law to impose stricter regulations on cosmeceuticals and the broader cosmetic industry is neither novel nor radical. Over the years, there have been many attempts to amend the FDCA and yet they have all been ultimately unsuccessful. However, in light of the growing market for cosmeceuticals, the ever-changing technologies used by cosmetics manufacturers, and the constantly developing pool of ingredients, the time is upon us to seriously evaluate how the FDA can better regulate modern

⁸⁶ Farren, *supra* note 6, at 393.

⁸⁷ Amatokin, <http://amatokinstore.com/about-amatokin.php>.

day cosmetics. Proposals that have been suggested in the past include “adjusting the existing cosmetic and drug regulatory categories, adding a third category, or requiring premarket testing.”⁸⁸ All have their own merits as well as their fair share of noteworthy critiques. However, what remains clear is that the current framework needs fixing.

Threatening to define every cosmetic product that offers drug-like effects, as a drug, is neither efficient nor ideal for providing consumers with the appropriate level of protection from physical and economic harm. The number of cosmeceutical products available on the market is enormous, and new products are continuously being launched. Without any forced requirements to register with the FDA, it is simply too difficult to fix the cosmeceutical problem with an after the fact type approach. Moreover simply requiring all cosmeceuticals to be regulated as de facto drugs by constructively inferring intended use based on the presence of an active ingredient is equally inefficient. Though this approach would be administratively easier from a classification standpoint, it would also result in “inordinately high resource expenditures, because proof of efficacy would be required even for those products about which relatively benign claims were made.”⁸⁹

Instead, given the term cosmeceutical is already widely recognized by the industry, consumers, dermatologists, academics and even the regulators, the FDA should formally acknowledge cosmeceuticals as a valid legal term. In

⁸⁸ Farren, *supra* note 6, at 397.

⁸⁹ Heymann, *supra* note 11, at 373.

providing legal recognition for cosmeceuticals as a distinct group of cosmetic products with drug-like qualities, the FDA can take its first step towards a better regulatory approach in handling these currently difficult-to-categorize products. Although introducing a new statutory definition is always difficult and contentious, the fact that this term already has a generally recognized colloquial meaning is helpful. Working off a definition proffered by Laura Heymann, cosmeceuticals could be defined as “those products containing an active ingredient for which cosmetic claims are made.”⁹⁰

Given the existent infrastructure and resource limitations, it may be favorable to introduce cosmeceuticals as a subgroup to either the cosmetics or drugs category. However, given the relatively lenient regulation of cosmetics and the overly restrictive regulation of drugs, the arguably better approach would be to create an altogether separate category for cosmeceuticals, which would be subject to its own set of regulations and requirements. In doing so, the FDA may want to use the Japanese model as a potential starting point. In Japan, a separate set of regulations exists to cover “cosmetic products with pharmacological action called quasidrugs, which are ranked between cosmetics and drugs.”⁹¹ The manufacturers of these quasidrugs are “required to obtain government approval before marketing, [which] is contingent upon a judgment by the Ministry of Health and Welfare regarding its adequacy as a quasidrug in view

⁹⁰ *Id.*

⁹¹ Kenkichi Oba, *Drugs versus Cosmetics: Cosmeceuticals?* in COSMECEUTICALS 241 (Peter Elsner & Howard I. Maibach, eds., 2000).

of its effectiveness, safety, etc.”⁹² Furthermore, the level of data and documentation that is required is directly contingent on the type of quasidrug being offered for approval; the indications and effects of the proposed product as well as the newness of the quasidrug all have a bearing on what is necessary for the review process.⁹³ Other Asian jurisdictions that have adopted a similar approach include Thailand, which distinctly regulates “controlled cosmetics” and Hong Kong, which has a category for “cosmetic-type drugs.”⁹⁴

Regardless of whether or not the FDA chooses to apply a similar approach as Japan in adopting some sort of sliding premarket approval process, there should at least be some base level of safety screening imposed on cosmeceuticals before they are allowed to go to market. Requiring companies to submit safety reports to a federal agency will help ensure uniformity across the market and make certain consumers are not exposed to dangerous cosmeceuticals. These reports could outline the types of testing that have been conducted by the companies, subject of course to some obligatory industry-level minimum, though these reports could be less extensive than the types of reports currently required for new drugs. In addition, like drug companies, manufacturers of cosmeceuticals should be required to participate in a mandatory registration process for all products and manufacturing establishments. Since there are heightened risks and potentially delayed effects that may stem from the use of

⁹² *Id* at 242-43.

⁹³ *Id* at 243.

⁹⁴ The Cosmetic World: A New Substrate for Pharmaceuticals,
<http://www.pharmainfo.net/reviews/cosmetic-world-new-substrate-pharmaceuticals>.

cosmeceuticals, having an accurate and up-to-date database of products and companies will aid the FDA in properly regulating cosmeceuticals on an on-going basis.

Finally, with regards to the aggressive marketing and shaky efficacy claims often made by cosmeceutical makers, consumers may also need additional economic protection as many of these cosmeceuticals cost a great deal more than traditional cosmetics (without the guarantee of effectiveness). If cosmeceuticals are regulated as a separate category and subject to premarket safety requirements, one option may be to require certain efficacy requirements be satisfied as well. However, because most of these products are still primarily focused on providing cosmetic (though increasing scientific) benefits rather than offering actual drug treatments, efficacy concerns will likely be less pressing for the FDA. Instead, one option the FDA may consider exploring is establishing some sort of uniform claims list to address commonly made cosmetic product claims. The FDA could set its own minimum standard of what constitutes a “dermatologist-tested” product or “hypoallergenic” cosmetic, and then require manufacturers to conform to the FDA level of expectation before they are permitted to make such claims in their product marketing. While this solution may present some budgetary concerns of its own in order to be effectively enforced, this option is likely less expensive than requiring the FDA to regulate and approve efficacy levels in cosmeceuticals. In turn, if manufacturers are confined in their ability to make confusing, unsubstantiated marketing claims in the

absence of meeting FDA thresholds, consumers will be afforded some additional protection from economic harm. Alternatively, the FDA could also come up with an enumerated list of tolerated claims for each type of cosmeceutical (e.g. anti-aging creams, eyelash enhancers etc.). Presumably, the tolerated claims would be more reserved than companies would ideally like. However, if a manufacturer wanted to assert greater claims in order to receive higher prices for its products, they would still have the option of marketing their product as a drug. But by limiting the realm of outlandish claims that a producer could make cosmeceutical products, the FDA may provide consumers with some much needed additional economic protection.

Part V: Conclusion

The modern cosmetics industry is rapidly changing. As science and technology become increasingly sophisticated, our society is witnessing a change in the types of cosmetic products that are offered on the marketplace today. Over the past few years, cosmeceuticals have grown significantly and they now represent the fastest growing segment of the personal care products industry. Thus as more and more cosmetics become increasingly drug-like in their composition and offerings, it is crucial for the law to finally catch up. Adhering to the old drug/cosmetic definitional distinction is no longer adequate when so many products blur the line. The FDA should no longer tolerate wildly divergent regulatory treatment of two similar products, which may occur under

the current system, simply based on the manufacturers' intended use for the products. Instead, in order to properly regulate this new generation of products, the FDCA should be amended to reflect a new category of regulations and requirements, specifically tailored to cosmeceutical products. By increasing the safety requirements imposed on cosmeceuticals and simultaneously limiting the ability of manufacturers to make overly inflated efficacy claims, consumers could be significantly better protected from physical and economic harms. The time is upon us to finally amend the FDCA and bring it in line with the modern day needs in the areas of cosmetics, drugs and cosmeceuticals.